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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,651	03/23/2001	David R. Walt	A-67209-4/RMS/DCF	6855

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EXAMINER
FORMAN, BETTY J

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/816,651	WALT ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 31 March 2004 in which claims 20, 22 and 25 were amended and claims 26-28 were added. All of the amendments have been thoroughly reviewed and entered.

The previous objections and rejections in the Office Action dated 4 December 2003 under 35 U.S.C. 112, second paragraph are withdrawn in view of the amendments. The previous rejections under 35 U.S.C. 102(b); 35 U.S.C. 102(e); 35 U.S.C. 103(a); and under obviousness-type double patenting are maintained as presented below

All of the arguments have been thoroughly reviewed and are discussed below. New grounds for rejection, necessitated by the added claims are discussed.

Claims 1-28 are under prosecution.

Specification

1. The amendment filed 31 March 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

"U.S.S.N. 09151,877, filed September 11, 1998, now U.S. Patent No. 6,327,410, issued on December 4, 2001".

2. The amendment to the first paragraph is also improper because all added text is not underlined as required by 37 CFR 1.121. The amendment was underlined as follows: "U.S.S.N. 0/9151,877, filed September 11, 1998, now U.S. Patent No. 6,327,410, issued on December 4, 2001". To be proper, the entire reference to the '877 application would be underline. This is not intended as an invitation to submit the amendment with correct underlining because as stated above and below, the amendment is objected to as new matter and as an improper claim for priority.

Applicant is required to cancel the new matter in the reply to this Office Action.

Priority

3. The amendment to the first paragraph cross-references "U.S.S.N. 09151,877, filed September 11, 1998. Applicant appears to be adding a new claim to priority. However, the '877 application was not cross-referenced in the first paragraph of the specification as originally filed. The '877 application was not listed on the Application Data Sheet (form 1.16b) submitted with the originally filed application on 23 March 2001. Hence, new priority claim is improper.

Applicant is reminded that claims for priority must be submitted within four months of the filing date or within sixteen months of the filing date of the priority application.

> If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted

during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

4. Applicant's claim for priority under 35 U.S.C. 120 is acknowledged. However, the subject matter of the instant Claims 1-12 and 16 i.e. a substrate other than a fiber optic bundle, is not disclosed in the parent applications as required under 35 U.S.C. 112. Therefore, instant Claims 1-12 and 16 are not entitled to the filing date of any of the above cited application. The effective filing date of instant Claims 1-12 and 16 is the filing date of the instant application i.e. 23 March 2001.

Response to Applicant's comments

5. Applicant comments regarding support for the instantly claimed "other than a fiber optic bundle" is acknowledged. However, Applicant only points to application 09/151,877 for support. The cited application is not a proper priority application. Hence, Applicant cannot rely on the application as a supporting disclosure. As stated above, the effective filing date for instant Claim 1-2 and 16 is the filing date of the instant application i.e. 23 March 2001.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-12 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Chee et al (WO 99/67641, published 29 December 1999).

Regarding Claim 1, Chee et al disclose the method of detecting a target analyte comprising providing an array comprising a substrate other than a fiber optic bundle (i.e. flat planar substrate, page 7, lines 15-32) and at least first and second sites comprising first and second reaction components (page 10, lines 14-24), contacting the array with a sample and detecting a change in an optical property around at least the first site as an indication of an interaction between the target and a reaction component (page 23, lines 1-22 and Claims 8-14).

Regarding Claim 2, Chee et al disclose the method wherein the target analyte is an enzyme (page 31, lines 31-35).

Regarding Claim 3, Chee et al disclose the method wherein the reaction components are enzyme substrates i.e. enzyme-specific interaction (page 10, lines 20-24 and page 34, lines 4-19).

Regarding Claim 4, Chee et al disclose the method wherein the reaction components are attached to microspheres with a non-cleavable linker (i.e. functional group, page 16, lines 1-18 and page 17, lines 6-13) and randomly distributed on the substrate (page 5, lines 24-27).

Regarding Claim 5, Chee et al disclose the method wherein the target analyte is an enzyme substrate i.e. the decoder binding ligand is a substrate (page 17, lines 15-34).

Regarding Claim 6, Chee et al disclose the method wherein the reaction components are enzymes i.e. identifier binding ligands (page 17, lines 15-34).

Regarding Claim 7, Chee et al disclose the method wherein the target analyte is an enzyme inhibitor i.e. the decoder binding ligand is an inhibitor (page 17, lines 15-34).

Regarding Claim 8, Chee et al disclose the method wherein the reaction components are enzymes i.e. identifier binding ligands (page 17, lines 15-34).

Regarding Claim 9, Chee et al disclose the method wherein the first and second reaction components are attached to first and second microspheres randomly distributed on the substrate (page 5, lines 3-7 and 24-27).

Regarding Claim 10, Chee et al disclose the method wherein the reaction components are enzymes (page 17, lines 7-13 and 28-34).

Regarding Claim 11, Chee et al disclose the method wherein the substrate is selected from the group consisting of glass, composite materials, metals and plastics (page 7, lines 15-24).

Regarding Claim 12, Chee et al disclose the method wherein the microspheres are distributed on the substrate providing a pattern of microspheres as spots on the array and hence, providing a spotted array (page 9, lines 1-24).

Regarding Claim 26, Chee et al disclose the method wherein detecting a change comprises detecting a released product around the reaction site (page 24, lines 1-24).

Response to Arguments

8. Applicant stated that the above rejection is improper because the filing date of the reference is after the priority date of the instant application. The argument has been considered but is not found persuasive for the reasons stated above regarding the new priority claim and effective filing date for the instant application.

9. Claims 19, 22 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Brenner (U.S. Patent No. 5,863,722, filed 7 June 1995).

Regarding Claim 19, Brenner discloses the method of detecting an enzymatic reaction comprising providing an array comprising an array substrate comprising discrete sites (i.e. positions, Column 25, lines 62-64) and a population of microspheres randomly distributed on the substrate comprising discrete oligonucleotides attached thereto, contacting the array with a composition comprising an enzyme (e.g. Fok I) and detecting a change in an optical property around at least the first site as an indication of an interaction between the enzyme and the oligonucleotide (Column 25, line 44-Column 26, line 50).

Regarding Claim 22, Brenner discloses the method wherein the product of the reaction comprises a label (Column 26, lines 46-50).

Regarding Claim 24, Brenner discloses the method wherein the substrate is glass (Column 25, lines 44-46).

Response to Arguments

10. Applicant asserts that the instant claims require monitoring a signal that is "remote from" or "released from" the microspheres and points to the specification (page 37, lines 8-30) to define the claimed "region surrounding the microspheres". Applicant states that in contrast to this requirement, Brenner teaches detection of a label on the microsphere. The argument has been considered but is not found persuasive. While limitations from the specification are not read into the claims, Brenner clearly teaches the claimed signal monitoring as defined by the specification. Brenner teaches excitation of the microparticles wherein fluorescence emitted **from** the microparticle is directed **through** a beam splitter, **to** distribution optics which, in turn, directs fluorescence **to** one or more suitable opto-electronic devices (Column 20, lines 8-26). Hence, Brenner clearly teaches monitoring a signal surrounding the microsphere i.e. released from the discrete site as defined by the specification.

11. Claims 1, 2, 10 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Van Ness et al (U.S. Patent No. 5,667,976, filed 14 February 1996).

Regarding Claim 1, Van Ness et al disclose the method of detecting a target analyte comprising providing an array comprising a substrate other than a fiber optic bundle (i.e. dipstick) and at least first and second sites comprising first and second reaction components (Column 10, lines 24-54), contacting the array with a sample and detecting a change in an optical property around at least the first site as an indication of an interaction between the target and a reaction component (Example 7, Column 21, line 20-Column 22, line 33).

Regarding Claim 2, Van Ness et al disclose the method wherein the target analyte is an enzyme (Column 6, lines 20-30 and Column 10, lines 49-54).

Regarding Claim 10, Van Ness et al disclose the method wherein the reaction components are enzymes (Column 6, lines 20-30 and Column 10, lines 49-54).

Regarding Claim 13, Van Ness et al disclose the method for detecting a target analyte comprising providing an array comprising an array substrate comprising discrete sites and a population of microspheres comprising at least a first and second subpopulation comprising reaction components (oligos) and detection molecule (biotin), contacting the array with a sample and detecting a change in optical property as an indication of interaction between the target and reaction component (Example 7, Column 21, line 20-Column 22, line 33).

Response to Arguments

12. Applicant asserts that the instant claims require monitoring a signal that is "remote from" or "released from" the microspheres and points to the specification (page 37, lines 8-30) to define the claimed "region surrounding the microspheres". Applicant states that in contrast to this requirement, Van Ness teaches detection of a label on a solid support but fails to detect a change in optical property surrounding a first site as claimed. The argument has been considered but is not found persuasive. While limitations from the specification are not read into the claims, Van Ness clearly teaches the claimed signal monitoring. Van Ness teaches label detection wherein the label is selected from fluorescent reporters (Column 11, lines 28-54) using available instrumentation. As illustrated above, instrumentation for detecting fluorescent labels detects emission from the label. Hence, Van Ness teaches the signal monitoring as claimed.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 18, 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenner (U.S. Patent No. 5,863,722, filed 7 June 1995).

Regarding Claim 18, Brenner teaches method of detecting an enzymatic reaction comprising providing an array comprising an array substrate comprising discrete sites (i.e. positions, Column 25, lines 62-64) and a population of microspheres randomly distributed on the substrate comprising reaction component substrates (i.e. oligos) attached thereto, contacting the array with a composition comprising reaction component (e.g. restriction enzyme, ligase) and detecting a change in an optical property around at least the first site as an indication of an interaction between the enzyme and the oligonucleotide (Column 25, line 44-Column 26, line 50). Brenner teaches the method wherein enzyme substrate (i.e. oligo) is attached to the microsphere and the enzyme is added to the immobilized substrate, but they do not teach an immobilized enzyme. However, the courts have stated that a mere reversal of parts is an obvious variation to a prior art arrangement see In re Gazda, 219 F.2d 449, 104 USPQ 400 (CCPA 1955) (MPEP § 2144.04 (VI) A). Therefore, the instantly claimed immobilized enzyme contacted with the enzyme substrate would have been obvious variation of the immobilized substrate contacted with the enzyme as taught by Brenner.

Regarding Claim 22, Brenner discloses the method wherein the product of the reaction comprises a label (Column 26, lines 46-50).

Regarding Claim 24, Brenner discloses the method wherein the substrate is glass (Column 25, lines 44-46).

Response to Arguments

15. Applicant reiterates the above argument regarding monitoring a signal released from the microsphere. The argument is not found persuasive because, as stated above, Brenner teaches excitation of the microparticles wherein fluorescence emitted **from** the microparticle is directed **through** a beam splitter, **to** distribution optics which, in turn, directs fluorescence **to** one or more suitable opto-electronic devices (Column 20, lines 8-26). Hence, Brenner clearly teaches monitoring a signal surrounding the microsphere i.e. released from the discrete site as defined by the specification.

16. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ness et al (U.S. Patent No. 5,667,976, filed 14 February 1996) in view of Urdea (U.S. Patent No. 4,775,619 issued 4 October 1988).

Regarding Claim 27, Van Ness et al disclose the method for detecting a target analyte comprising providing an array comprising an array substrate comprising discrete sites and a population of microspheres comprising at least a first and second subpopulation comprising reaction components (oligos) and detection molecule (biotin), contacting the array with a sample and detecting a change in optical property as an indication of interaction between the target and reaction component (Example 7, Column 21, line 20-Column 22, line 33) wherein the label and detection is selected from one of many known in the art (Column 11, lines 33-53) but they do not specifically teach detecting a released reaction product. However, detecting a change in optical property resulting from released reaction product was well known in the art at the time the claimed invention was made as taught by Urdea.

Urdea teach a similar method for detecting a target comprising providing a substrate comprising reaction components immobilized at sites on the substrate, contacting the substrate with a sample and detecting a change in optical property around the site as an indication of target-reaction component interaction wherein the change in optical property results from a released reaction product (Column 5, lines 25-51; Column 6, lines 41-53; Column 11, lines 5-67; and Fig. 1). Urdea further teach their method for detecting released reaction product reduces false positives and background measurements thereby providing accurate and economical diagnostics (Column 17, lines 36-59).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the detection of released reaction product taught by Urdea to the label detection taught by Van Ness for the expected benefit of reducing false positives and background measurements thereby providing accurate and economical diagnostics as taught by Urdea (Column 17, lines 36-59).

17. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brenner (U.S. Patent No. 5,863,722, filed 7 June 1995).

. Regarding Claim 28, Brenner discloses the method of Claims 18 and 19 as discussed above comprising detecting an enzymatic reaction comprising providing an array comprising an array substrate comprising discrete sites (i.e. positions, Column 25, lines 62-64) and a population of microspheres randomly distributed on the substrate comprising discrete oligonucleotides attached thereto, contacting the array with a composition comprising an

enzyme (e.g. Fok I) and detecting a change in an optical property around at least the first site as an indication of an interaction between the enzyme and the oligonucleotide (Column 25, line 44-Column 26, line 50) but they do not specifically teach detecting a released reaction product. However, detecting a change in optical property resulting from released reaction product was well known in the art at the time the claimed invention was made as taught by Urdea.

Urdea teach a similar method for detecting a target comprising providing a substrate comprising reaction components immobilized at sites on the substrate, contacting the substrate with a sample and detecting a change in optical property around the site as an indication of target-reaction component interaction wherein the change in optical property results from a released reaction product (Column 5, lines 25-51; Column 6, lines 41-53; Column 11, lines 5-67; and Fig. 1). Urdea further teach their method for detecting released reaction product reduces false positives and background measurements thereby providing accurate and economical diagnostics (Column 17, lines 36-59).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the detection of released reaction product taught by Urdea to the label detection taught by Brenner for the expected benefit of reducing false positives and background measurements thereby providing accurate and economical diagnostics as taught by Urdea (Column 17, lines 36-59).

Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 13-14 and 18-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39-40 and 51 of U.S. Patent No. 6,023,540. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of detecting a target analyte (e.g. enzyme) comprising providing populations of microspheres having functionalities, contacting the microspheres with a sample and detecting optical signal to determine presence of the analyte. The claims only differ in the arrangement of the limitations within the claims. For example, the instant claims recite a) providing an array comprising microspheres, b) contacting the array with a sample and c) determining the presence of the analyte. While the '540 claims recite, a) contacting a sample with a substrate (limited to an array in Claim 40) comprising microspheres and b) determining the presence of the analyte. Because the claims differ only in the arrangement of the limitations within the claims, the claims are not patentably distinct.

20. Claims 13-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14, 18 and 21 of U.S. Patent No. 6,266,459. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of detecting a target analyte (e.g. enzyme) comprising providing populations of microspheres having functionalities,

contacting the microspheres with a sample and detecting optical signal to determine presence of the analyte. The claims only differ in the arrangement of the limitations within the claims. For example, the instant claims recite a) providing an array (limited to fiber optic bundle in Claim 23) comprising microspheres, b) contacting the array with a sample and c) detecting a signal around a microsphere to determine the presence of the analyte. While the '459 claims recite a) providing a population of microspheres distributed on a surface (limited to fiber optic bundle in Claim 2), b) contacting the microspheres with a sample, and c) detecting a signal around a microsphere to determine the presence of the analyte. Because the claims differ only in the arrangement of the limitations within the claims, the claims are not patentably distinct.

21. Claims 13, 18, 19 and 23-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17- 21 of U.S. Patent No. 6,327,410. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of detecting a target analyte comprising providing populations of microspheres having functionalities, contacting the microspheres with a sample and detecting optical signal to determine presence of the analyte. The claims only differ in the arrangement of the limitations within the claims. For example, the instant claims recite a) providing an array (limited to fiber optic bundle in Claim 23) comprising microspheres, b) contacting the array with a sample and c) detecting a signal around a microsphere to determine the presence of the analyte. While the '410 claims recite a) contacting a sample with a substrate (limited to fiber optic substrate in Claim 18) comprising microspheres and b) determining the presence of the analyte. Because the claims differ only in the arrangement of the limitations within the claims, the claims are not patentably distinct.

22. Claims 13, 18, 19 and 23-25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-21 of copending Application No. 09/925,292. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of detecting a target analyte comprising providing populations of microspheres having functionalities, contacting the microspheres with a sample and detecting optical signal to determine presence of the analyte. The claims only differ in the arrangement of the limitations within the claims. For example, the instant claims recite a) providing an array (limited to fiber optic bundle in Claim 23) comprising microspheres, b) contacting the array with a sample and c) detecting a signal around a microsphere to determine the presence of the analyte. While the '410 claims recite a) contacting a sample with a substrate (limited to fiber optic substrate in Claim 18) comprising microspheres and b) determining the presence of the analyte. Because the claims differ only in the arrangement of the limitations within the claims, the claims are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Additional Comments

23. Applicant states that upon indication of allowable subject matter, terminal disclaimers will be filed. Applicant's statement is acknowledged. The above rejections are maintained.

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

25. No claim is allowed.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
June 18, 2004